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|---|-------------|----------------------|---------------------|------------------|
| APPLICATION NO.                         | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/534,894                              | 05/13/2005  | Xiangyin Kong        | 186660/US           | 4722             |
| 52835                                   | 7590        | 05/23/2008           | EXAMINER            |                  |
| HAMRE, SCHUMANN, MUELLER & LARSON, P.C. |             |                      | SHAFER, SHULAMITH H |                  |
| P.O. BOX 2902                           |             |                      | ART UNIT            | PAPER NUMBER     |
| MINNEAPOLIS, MN 55402-0902              |             |                      | 1647                |                  |
| MAIL DATE                               |             | DELIVERY MODE        |                     |                  |
| 05/23/2008                              |             | PAPER                |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |  |                                    |
|------------------------------|--|------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/534,894   | <b>Applicant(s)</b><br>KONG ET AL. |
|                              | <b>Examiner</b><br>SHULAMITH H. SHAFER | <b>Art Unit</b><br>1647            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on **14 February 2008**.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) **13-18,25 and 26** is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) **13-18,25 and 26** is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/1449)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **Detailed Action**

#### ***Status of Application, Amendments, And/Or Claims:***

Applicants' amendment, received 14 February 2008 is acknowledged and entered. Claims 20 and 27-33 have been cancelled.

Claims 13-18, 25 and 26 are pending in the instant invention.

### **Objections**

The specification is objected to because it contains numerous typographical, spelling and grammatical errors. Examples of some errors are found on: page 2, line 31 ("without fair", "little fair" should be corrected to "without hair" and "little hair") page 11, line 19 ("without fair, mice with little fair, and mice with normal fair" should be amended to read "without hair, mice with little hair and mice with normal hair"). Appropriate correction is required.

### **Rejections**

#### ***35 U.S.C. §§ 101 and 112, First Paragraph***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1647

Claims 13-18, 25 and 26 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial or specific asserted utility or a well established utility.

When determining whether an applicant has described the utility of invention, one has to determine whether the applicant has described a well-established utility. If not, has the application made any assertion of specific, substantial and credible utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for use. In contrast to general utility, a specific utility will be specific to the claimed subject matter. A substantial utility defines a real world utility of the invention and utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context use are not substantial utility (see utility guidelines, in Federal Register January 5, 2001, Volume 66, Number 5, Pages 1092-1099).

The claims of the instant invention are drawn to an isolated polynucleotide sequence encoding the polypeptide comprising the amino acid sequence of SEQ ID NO:2, a vector comprising said nucleic acid, a host cell comprising the vector, an isolated polypeptide comprising or consisting of the amino acid sequence of SEQ ID NO:2 and a method of producing said polypeptide. In order to establish utility for the instant invention, one must establish a substantial, specific or well established utility for the polypeptide of SEQ ID NO:2, the polypeptide of the instant invention which is encoded by the polynucleotide of the instant invention.

The specification teaches the recombinant protein, named Rhor, (identified as a mutation in the wildtype Balb/c mouse) may be used to screen antibodies, polypeptides or ligands as binding partners for Rhor [paragraph 0059 of PGPUB 20060039884, the PGPUB of the instant invention] and to prepare antibodies [Example 1]. These asserted utilities are not specific or substantial, since any polypeptide may be utilized to identify binding partners or generate antibodies and further research would be required to identify a real-world context of use.

The polynucleotides and polypeptides of the instant invention also lack a well-established utility. The specification discloses that the polynucleotides and polypeptides

Art Unit: 1647

of the instant invention could be used in the diagnosis and treatment of Rhor related diseases [paragraph 0075], and to cure diseases caused by low or no activity of Rhor protein such as baldness [paragraphs 0059 and 0078]. However, applicant has not identified any Rhor-related diseases (other than baldness) and has not provided evidence of a nexus between changes in expression or activity of Rhor protein and any human disease, or any type of human baldness. The disclosure teaches a gene, which applicants have identified as Rhor, wherein mutations of said gene is associated with baldness [paragraph 0021]. The Rhor mutation was identified in "hairless" Balb/c mice; heterozygous mice exhibit sparse hair, while homozygotes are hairless [paragraph 0081]. DNA encoding the mutant protein comprises a 230 bp deletion in the genomic sequence of DNA encoding the wild-type protein [paragraph 0092]. However, applicants have not provided evidence of a human homologue of the protein of the instant invention, nor shown any evidence that such a protein is associated with any type of baldness in humans. Merely showing that a gene is *necessary* for hair growth does not make it predictable that the gene or protein encoded thereby could be used to encourage hair growth or prevent hair loss.

The art teaches that there are many causes of hair loss or baldness. Springer et al (2003. American Family Phys. 68:93-102, cited in previous Office Action) teach that among the common forms of hair loss are androgenetic alopecia, syphilis, trichotillomania, alopecia universalis, telogen effluvium, toxic exposure, chemotherapy, metabolic derangements, alopecia totalis, alopecia areata, tinea capitis, traction alopecia and cicatricial alopecia (page 95, Figure 1). Thus, one would not be able to predict that administration of a polypeptide of SEQ ID NO:2 would be able to treat individuals suffering from hair loss of any etiology. The art teaches (see, for example, Ahmad et al 1998. Science 279:720-724) that there are several forms of hereditary human hair loss (alopecias), which may represent a dysregulation of the cycle of hair growth and remodeling, yet the molecular basis of many of the alopecias is unknown (page 720, 3<sup>rd</sup> column, 2<sup>nd</sup> paragraph). Ahmed et al. have identified the alopecia locus in a large family exhibiting simple, recessive alopecia universalis and the protein

Art Unit: 1647

encoded by this gene; this protein shows significant homology to the mouse and rat *hairless* protein. However, this protein has not been shown as having any degree of homology to the Rhor polypeptide of the instant invention.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. CT, 1966). The court found that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Thus, the evidence presented does not establish a substantial and specific or a well established utility for the polynucleotides or polypeptides of the instant invention, but is an invitation to further experimentation to establish the function of polynucleotide of SEQ ID NO:1 and the polypeptide of SEQ ID NO:2 and if said molecules would be useful in treating baldness.

Claims 13-18, 25 and 26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Conclusion:***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHULAMITH H. SHAFFER whose telephone number is (571)272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao, Ph.D. can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/, Ph.D.  
Primary Examiner, Art Unit 1647

/Shulamith H. Shafer, Ph.D./  
Examiner, Art Unit 1647